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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
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| 10/500,454 | 02/08/2005 | Monique Berwaer | 2004_0980A | 2307 |

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| EXAMINER | |
|---|---|
| SILVERMAN, ERIC E | |

| ART UNIT | PAPER NUMBER |
|---|---|
| 1618 | |

| MAIL DATE | DELIVERY MODE |
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| 12/18/2008 | PAPER |

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

| Office Action Summary | Application No. | Applicant(s) | |
|---|---|---|---|
| | 10/500,454 | BERWAER ET AL. | |
| | Examiner | Art Unit | |
| | ERIC E. SILVERMAN | 1618 | |

*-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --*

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

1)☒ Responsive to communication(s) filed on *25 September 2008*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

4)☒ Claim(s) *3,6,8-10,14-18 and 20-22* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *3,6,8-10,14-18 and 20-22* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

**Application Papers**

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

## DETAILED ACTION

### *Continued Examination Under 37 CFR 1.114*

A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 8-14-08 has been entered.

### *Claim Rejections - 35 USC § 103*

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

Claims 3, 6, 8-10, 14-18, and 20-22 are rejected under 35 U.S.C. 103(a) as being unpatentable over 5,043,167 to Rotini in view of DERWENT-ACC-NO 1999-585815 (the '815 reference), US 5,869,479 to Kretner, US 3,906,086 to Guy and US 6,274,168 to Addicks.

It would have been prima facie obvious to a person of ordinary skill in the art at the time of the invention to use the specified materials in their specified amounts to give a dual IR/PR release efletirizine dosage form. The art, taken as a whole, indicates that: (1) Dual IR/PR dosage forms are well known generally, and are specifically known for drugs such as diclogenac, which is used for treating rhinitis. (2) Eflitirazine is also used

for treating rhinitis. Appropriate dosing of eflitirazine is known or a readily determinable optimizable parameter by the artisan. (3) The excipients recited in the claims are known for use in IR or PR (as the case may be) portions of tablets. As such, the instant claims represent no more than substitution of one drug used against rhinitis for another drug used against rhinitis in a dual IR/PR dosage form, and optimization of the type and amounts of the excpients, wherein the excipients used in the claims are already recognized for use in IR or PR dosage forms.

Claims 3, 6, 8-10, 14-18, and 29-22 is rejected under 35 U.S.C. 103(a) as being unpatentable over ,043,167 to Rotini in view of DERWENT-ACC-NO 1999-585815 (the '815 reference), US 5,869,479 to Kretner, US 3,906,086 to Guy and US 6,274,168 to Addicks and in further view of US 49,966,768.

The teachings of Rotini, the 815 reference, Kretner, Guy and Addicks was discussed in a previous office action. What is lacking in those first several references is the matrix agent of claim 19. The teachings of '768 have been discussed previously. Notably, this reference teaches the use of HPMC in prolonged release fractions in combination with EC, and gives guidance on how much HPMC to use. Regarding the new limitations specific amounts (in mg) of the various components, the art teaches that each of these components is a commonly used excipient in IR or PR fractions of dosage forms. Finding the optimal or workable amount of a material when the art provides the general parameters is not a basis for patentability.

It would have been prima facie obvious to a person of ordinary skill in the art at the time of the invention to use HPMC in the prolonged release fraction, as such use is

no more than using HPMC for its art known purpose, and giving predictable results. It would have been prima facie obvious to a person of ordinary skill in the art at the time of the invention to use the specified materials in their specified amounts to give a dual IR/PR release efletirizine dosage form. The art, taken as a whole, indicates that: (1) Dual IR/PR dosage forms are well known generally, and are specifically known for drugs such as diclogenac, which is used for treating rhinitis. (2) Eflitirazine is also used for treating rhinitis. Appropriate dosing of eflitirazine is known or a readily determinable optimizable parameter by the artisan. (3) The excipients recited in the claims are known for use in IR or PR (as the case may be) portions of tablets. As such, the instant claims represent no more than substitution of one drug used against rhinitis for another drug used against rhinitis in a dual IR/PR dosage form, and optimization of the type and amounts of the excpients, wherein the excipients used in the claims are already recognized for use in IR or PR dosage forms.

***Response to Arguments***

Applicants' arguments have been fully considered, but are not persuasive. Applicants point to the declaration of 2/23/2007, and argue that the instant claims are now commensurate in scope with the showing of that declaration. In response, it is noted that the results that are said to be unexpected in the declaration occur after administration of an IR solution of eflitirazine followed by a PR tablet. The claims are directed to a single dosage form having IR and PR portions. An IR solution is not commensurate with an IR portion of a tablet, and there is no evidence to indicate that the pharmacodynamics of a solution are replicated in instantly claimed dual release

dosage form. The release of drug from solution does not depend on disintegration of the excipients, as in a solid or tablet form. Furthermore, the alleged unexpected results appear to be linked to both the nature of the IR and PR forms (it follows logically that the Cmax of a drug taken in either a dual IR/PR form or a IR solution and a PR tablet will have more of a relationship to the nature of the IR part than the PR part, as the IR part will release drug quickly, building to a particular Cmax, and then PR part will then maintain a therapeutically effective amount of drug over a prolonged time). Because the IR form in the example is so different from the IR form in the claims, the claims cannot be said to be commensurate in scope with the showing.

## ***Conclusion***

No claims are allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to ERIC E. SILVERMAN whose telephone number is (571)272-5549. The examiner can normally be reached on Monday to Thursday 7:00 am to 5:00 pm and Friday 7:00 am to noon.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael Hartley can be reached on 571 272 0616. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Eric E Silverman/
Examiner, Art Unit 1618